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Counsel for Plaintiff
KYTHERA BIOPHARMACEUTICALS, INC.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

KYTHERA BIOPHARMACEUTICALS, INC.,

Plaintiff,

v.

SLAYBACK PHARMA LLC,

Defendant.

Civil Action No. _____

Jury Trial Demanded

Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Kythera Biopharmaceuticals, Inc. ("Plaintiff" or "Kythera") by their undersigned attorneys, Fish & Richardson P.C. and Walsh Pizzi O'Reilly Falanga, hereby allege as follows:

The Nature of the Action

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant Slayback Pharma LLC ("Slayback" or "Defendant"). This action arises out of the filing by Slayback of Abbreviated New Drug Application ("ANDA") No. 212296 with the United States Food and Drug Administration ("FDA").
2. In ANDA No. 212296, Slayback seeks approval to market a generic version of Kythera's Kybella® product (the "Slayback ANDA Product"), prior to the expiration of U.S.

Patent Nos. 8,101,593 (the “‘593 patent”); 8,367,649 (the “‘649 patent”); and 8,653,058 (the “‘058 patent”).

The Parties

3. Kythera Biopharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 5 Giralda Farms, Madison, NJ 07940.

4. On information and belief, defendant Slayback Pharma LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 301 Carnegie Center, #303, Princeton, New Jersey 08540.

5. On information and belief, Slayback, itself and through its subsidiaries, affiliates, and agents, manufactures, distributes, and/or imports generic pharmaceutical products for sale and use throughout the United States, including in this District.

6. On information and belief, Slayback prepared and filed ANDA No. 212296 and will be involved in the manufacture, importation, marketing, and sale of the Slayback ANDA Product in the United States, including this District, if ANDA No. 212296 is approved.

Jurisdiction and Venue

7. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

8. This Court has personal jurisdiction over Slayback by virtue of its substantial, systematic, and continuous contacts with this jurisdiction, as alleged herein. On information and belief, Slayback develops, formulates, manufactures, imports, offers for sale, sells, commercializes, markets, and/or distributes generic pharmaceutical products in or into the United States, including in or into the State of New Jersey.

9. On information and belief, Slayback prepared and filed ANDA No. 212296, seeking approval from FDA to sell the Slayback ANDA Product throughout the United States, including within the State of New Jersey, and to derive substantial revenue therefrom. Plaintiff has been injured in New Jersey because of Defendant's ANDA filing.

10. By submitting ANDA No. 212296 to FDA, Slayback has made clear that it intends to market the Slayback ANDA Product in the State of New Jersey. If ANDA No. 212296 is approved, the Slayback ANDA Product would, among other things, be marketed and distributed in the State of New Jersey, and/or prescribed by physicians practicing and dispensed by pharmacies located within the State of New Jersey, all of which would have a substantial effect on the State of New Jersey.

11. On information and belief, Slayback participated in the preparation and/or filing of ANDA No. 212296, seeking approval from FDA to sell the Slayback ANDA Product throughout the United States, including within the State of New Jersey.

12. Slayback therefore committed an act of infringement in the State of New Jersey by participating in the preparation, filing and submission of ANDA No. 212296 pursuant to § 505(j) of the Federal Food Drug and Cosmetic Act to FDA, accompanied by a Paragraph IV certification.

13. This Court has personal jurisdiction over Slayback because, on information and belief, Slayback regularly and continuously transacts business and/or solicits business in this District, including by offering for sale, selling and/or distributing pharmaceutical products in the State of New Jersey, either on its own or through its subsidiaries, affiliates, and/or agents, and/or derives substantial revenue from the sale of its products in the State of New Jersey.

14. This Court also has personal jurisdiction over Slayback because it is registered to do business in the State of New Jersey and it has its principal place of business in New Jersey.

15. On information and belief, Slayback avails itself of the benefits and protections of the laws of the State of New Jersey. For example, Slayback is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration No. 5005359.

16. On or about September 27, 2018, a letter, dated September 26, 2018 from Slayback (the “Notice Letter”) was received. The Notice Letter states that Slayback had submitted, and FDA had received, an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). On information and belief, Slayback prepared the Notice Letter in the State of New Jersey and sent the Notice Letter from its New Jersey place of business located at 301 Carnegie Center, #303 Princeton, New Jersey 08540.

17. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) because Slayback committed an act of infringement in this District and has a regular and established place of business in this District. Slayback submitted its ANDA No. 212296 pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act, and, upon receiving approval of its ANDA, will manufacture, sell, offer to sell, and/or import the Slayback ANDA Product in the United States, including in this District. On information and belief, Slayback also prepared its ANDA and Notice Letter in the State of New Jersey. Slayback has thus committed an act of infringement in this District. On information and belief, Slayback also has regular and established places of business in this District located at 301 Carnegie Center, Suite 303, Princeton New Jersey 08540.

Patents-in-Suit

18. On January 24, 2012, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,101,593 (the “’593 patent”), titled “Formulations of Deoxycholic Acid and Salts Thereof.” A true and correct copy of the ’593 patent is attached hereto as Exhibit A. The claims of the ’593 patent are valid, enforceable and not expired. Kythera Biopharmaceuticals, Inc. is the assignee of the ’593 patent, and is the owner of all right, title, and interest in the ’593 patent.

19. On February 5, 2013, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,367,649 (the “’649 patent”), titled “Formulations of Deoxycholic Acid and Salts Thereof.” A true and correct copy of the ’649 patent is attached hereto as Exhibit B. The claims of the ’649 patent are valid, enforceable and not expired. Kythera Biopharmaceuticals, Inc. is the assignee of the ’649 patent, and is the owner of all right, title, and interest in the ’649 patent.

20. On February 18, 2014, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,653,058 (the “’058 patent”), titled “Compositions Comprising Deoxycholic Acid and Salts Thereof Suitable for Use in Treating Fat Deposits.” A true and correct copy of the ’058 patent is attached hereto as Exhibit C. The claims of the ’058 patent are valid, enforceable and not expired. Kythera Biopharmaceuticals, Inc. is the assignee of the ’058 patent, and is the owner of all right, title, and interest in the ’058 patent.

Acts Giving Rise to this Action

21. Kythera Biopharmaceuticals, Inc. holds New Drug Application (“NDA”) No. 206333 for the use of deoxycholic acid injection for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.

22. The deoxycholic acid injection approved under the NDA is marketed in the United States under the trade name Kybella®. FDA’s publication *Approved Drug Products with*

Therapeutic Equivalence Evaluations (commonly known as the “Orange Book”) identifies the following patents as covering Kybella®: U.S. Patent Nos. 7,622,130; 7,754,230; 8,101,593; 8,242,294; 8,298,556; 8,367,649; 8,461,140; 8,546,367; 8,653,058; 8,846,066; 8,883,770; 9,522,155; 9,636,349; and 9,949,986.

23. As described above, on or around October 1, 2018, the Notice Letter was received, stating that Slayback had submitted, and FDA had received, ANDA No. 212296.

24. The Notice Letter further states that Slayback has submitted ANDA No. 212296 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Slayback ANDA Product before the expiration of U.S. Patent Nos. 8,101,593; 8,242,294; 8,367,649; 8,461,140; 8,546,367; 8,653,058; 8,883,770; 9,522,155; 9,636,349; and 9,949,986.

25. In the Notice Letter, Slayback states that its ANDA includes a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A) with respect to the ’593, ’294, ’649, ’140, ’367, ’058, ’770, ’155, ’349 and ’986 patents. The Notice Letter further alleges that these patents are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Slayback’s ANDA Product in the United States.

26. In the Notice Letter, Slayback states that the Slayback ANDA Product does not infringe the claims of the ’294, ’140, ’367, ’349, ’770, ’155 and ’986 patents. The Notice Letter also states that claims 1 and 3-15 of the ’058 patent would not be infringed. Slayback does not contest infringement of claim 2 of the ’058 patent. Slayback also does not contest infringement of the ’593 and ’649 patents. Based on review of documents produced by Slayback under its Offer of Confidential Access, the Slayback ANDA Product infringes at least one claim of each the ’058, ’593 and ’649 patents.

27. The Notice Letter is silent with regard to four other patents listed in the Orange Book related to Kybella®: U.S. Patent Nos. 7,622,130; 7,754,230; 8,298,556 and 8,846,066. On information and belief, Slayback has submitted a Paragraph III certification with regard to U.S. Patent Nos. 7,622,130; 7,754,230; 8,298,556 and 8,846,066.

28. By filing ANDA No. 212296, Slayback has necessarily represented to FDA that the Slayback ANDA Product has the same active ingredient as Kybella®, has the same dosage form and strength as Kybella®, and is bioequivalent to Kybella®.

29. On information and belief, Slayback is seeking approval to market the Slayback ANDA Product for the same approved indication as Kybella®.

30. On information and belief, the FDA has not yet approved Slayback's ANDA No. 212296.

31. On information and belief, Slayback has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and /or import a generic version of Kythera's Kybella® product before expiration of the patents-in-suit.

32. On information and belief, Slayback continues to seek approval of ANDA No. 212296 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of its proposed generic version of Kythera's Kybella® product.

33. On information and belief, following FDA approval of its ANDA No. 212296, Slayback will sell the approved generic version of Kythera's Kybella® product throughout the United States, including in New Jersey.

34. Under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter in order to receive certain benefits

under the Act, including a stay of approval of the generic drug for up to 30 months during the pendency of litigation, as appropriate. 21 U.S.C. § 355(c)(3)(c).

35. This action is being commenced before the expiration of the 45 days from the date Kythera received the Notice Letter, which triggers a stay of FDA approval of Slayback's ANDA No. 212296, pursuant to 21 U.S.C. § 355(J)(5)(B)(iii).

Count I

(Infringement of the '593 Patent Under 35 U.S.C. § 271(e)(2) by Slayback's ANDA Product)

36. Kythera incorporates each of the preceding paragraphs as if fully set forth herein.

37. Pursuant to 35 U.S.C. § 271(e)(2)(A), Slayback has committed an act of infringement with respect to the '593 patent by submitting ANDA No. 212296 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Slayback ANDA Product in the United States prior to the expiration of the '593 patent.

38. Slayback's commercial manufacture, use, offer for sale, sale, and/or importation of the Slayback ANDA Product as described in ANDA No. 212296 prior to the expiration of the '593 patent would constitute infringement of the '593 patent

39. On information and belief, Slayback became aware of the '593 patent no later than the date on which that patent was listed in the Orange Book.

40. On information and belief, Slayback knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product will actively induce and contribute to the actual infringement of the '593 patent.

41. On information and belief, Slayback knows or should know that its ANDA Product will be especially made for or especially adapted for use in infringement of the '593 patent, and is not a staple article or commodity of commerce suitable for substantial non-

infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product will actively contribute to the actual infringement of the '593 patent.

42. The commercial manufacture, use, offer for sale, sale and/or importation of Slayback's ANDA Product as described in ANDA No. 212296 in violation of Kythera's patent rights will cause harm to Kythera for which damages are inadequate.

Count II

(Declaratory Judgment of Infringement of the '593 Patent under 35 U.S.C. § 271(a) by Slayback's ANDA Product)

43. Kythera incorporates each of the preceding paragraphs as if fully set forth herein.

44. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

45. There is an actual case or controversy such that the Court may entertain Kythera's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

46. The commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's ANDA Product described in ANDA No. 212296 will constitute an act of direct infringement of one or more claims of the '593 patent.

47. On information and belief, Slayback will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product described in ANDA No. 212296 immediately and imminently upon approval of ANDA No. 212296.

48. The foregoing actions by Slayback will constitute infringement of the '593 patent.

49. Slayback will commit those acts of infringement without license or authorization.

50. Kythera is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Slayback's ANDA Product described in ANDA No. 212296 by Slayback will infringe the '593 patent.

51. Unless Slayback is enjoined from infringing the '593 patent, Kythera will suffer irreparable injury for which damages are an inadequate remedy.

Count III

(Declaratory Judgment of Infringement of the '593 Patent under 35 U.S.C. § 271(b) and (c) by Slayback's ANDA Product)

52. Kythera incorporates each of the preceding paragraphs as if fully set forth herein.

53. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

54. There is an actual case or controversy such that the Court may entertain Kythera's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

55. Slayback has knowledge of the '593 patent.

56. On information and belief, Slayback became aware of the '593 patent no later than the date on which that patent was listed in the Orange Book.

57. On information and belief, Slayback has acted with full knowledge of the '593 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '593 patent.

58. The commercial manufacture, use, sale, offer for sale, and/or importation of Slayback's ANDA Product as described in ANDA No. 212296 will induce the actual infringement of the '593 patent.

59. On information and belief, Slayback knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its ANDA Product described in ANDA No. 212296 will actively induce the actual infringement of the '593 patent.

60. On information and belief, Slayback will encourage another's infringement of the '593 patent by and through the commercial manufacture, use, sale, offer for sale, and/or

importation of its ANDA Product as described in ANDA No. 212296, which is covered by certain claims of the '593 patent.

61. Slayback's acts of infringement will be done with knowledge of the '593 patent and with the intent to encourage infringement.

62. The foregoing actions by Slayback will constitute active inducement of infringement of the '593 patent.

63. On information and belief, Slayback knows or should know that its ANDA Product as described in ANDA No. 212296 will be especially made or especially adapted for use in an infringement of the '593 patent, and is not a staple article or commodity suitable for substantial non-infringing use.

64. The commercial manufacture, use, sale, offer for sale, and/or importation of Slayback's ANDA Product described in ANDA No. 212296 will contribute to the actual infringement of the '593 patent.

65. On information and belief, Slayback knows or should know that its offer for sale, sale, and/or importation of its ANDA Product as described in ANDA No. 212296 will contribute to the actual infringement of the '593 patent.

66. The foregoing action by Slayback will constitute contributory infringement of the '593 patent.

67. On information and belief, Slayback intends to, and will, actively induce and contribute to the infringement of the '593 patent when ANDA No. 212296 is approved, and plans and intends to, and will do so immediately and imminently upon approval.

68. Kythera is entitled to a declaratory judgement that future commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's ANDA Product as

described in ANDA No. 212296 will induce and/or contribute to the infringement of the '593 patent.

69. The commercial manufacture, use, offer for sale, sale and/or importation of Slayback's ANDA Product described in ANDA No. 212296, which will actively induce and/or contribute to infringement of the '593 patent, in violation of Kythera's patent rights, will cause harm to Kythera for which damages are inadequate.

70. Unless Slayback is enjoined from actively inducing and contributing to the infringement of the '593 patent, Kythera will suffer irreparable injury for which damages are an inadequate remedy.

71. On information and belief, despite having actual notice of the '593 patent, Slayback continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '593 patent in disregard of Kythera's rights, making this case exceptional and entitling Kythera to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count IV

(Infringement of the '649 Patent Under 35 U.S.C. § 271(e)(2) by Slayback's ANDA Product)

72. Kythera incorporates each of the preceding paragraphs as if fully set forth herein.

73. Pursuant to 35 U.S.C. § 271(e)(2)(A), Slayback has committed an act of infringement with respect to the '649 patent by submitting ANDA No. 212296 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Slayback ANDA Product in the United States prior to the expiration of the '649 patent.

74. Slayback's commercial manufacture, use, offer for sale, sale, and/or importation of the Slayback ANDA Product as described in ANDA No. 212296 prior to the expiration of the '649 patent would constitute infringement of the '649 patent

75. On information and belief, Slayback became aware of the '649 patent no later than the date on which that patent was listed in the Orange Book.

76. On information and belief, Slayback knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product will actively induce and contribute to the actual infringement of the '649 patent.

77. On information and belief, Slayback knows or should know that its ANDA Product will be especially made for or especially adapted for use in infringement of the '649 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product will actively contribute to the actual infringement of the '649 patent.

78. The commercial manufacture, use, offer for sale, sale and/or importation of Slayback's ANDA Product as described in ANDA No. 212296 in violation of Kythera's patent rights will cause harm to Kythera for which damages are inadequate.

Count V

(Declaratory Judgment of Infringement of the '649 Patent under 35 U.S.C. § 271(a) by Slayback's ANDA Product)

79. Kythera incorporates each of the preceding paragraphs as if fully set forth herein.

80. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

81. There is an actual case or controversy such that the Court may entertain Kythera's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

82. The commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's ANDA Product described in ANDA No. 212296 will constitute an act of direct infringement of one or more claims of the '649 patent.

83. On information and belief, Slayback will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product described in ANDA No.

212296 immediately and imminently upon approval of ANDA No. 212296.

84. The foregoing actions by Slayback will constitute infringement of the '649 patent.

85. Slayback will commit those acts of infringement without license or authorization.

86. Kythera is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Slayback's ANDA Product described in ANDA No. 212296 by Slayback will infringe the '649 patent.

87. Unless Slayback is enjoined from infringing the '649 patent, Kythera will suffer irreparable injury for which damages are an inadequate remedy.

Count VI

(Declaratory Judgment of Infringement of the '649 Patent under 35 U.S.C. § 271(b) and (c) by Slayback's ANDA Product)

88. Kythera incorporates each of the preceding paragraphs as if fully set forth herein.

89. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

90. There is an actual case or controversy such that the Court may entertain Kythera's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

91. Slayback has knowledge of the '649 patent.

92. On information and belief, Slayback became aware of the '649 patent no later than the date on which that patent was listed in the Orange Book.

93. On information and belief, Slayback has acted with full knowledge of the '649 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '649 patent.

94. The commercial manufacture, use, sale, offer for sale, and/or importation of Slayback's ANDA Product as described in ANDA No. 212296 will induce the actual infringement of the '649 patent.

95. On information and belief, Slayback knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its ANDA Product described in ANDA No. 212296 will actively induce the actual infringement of the '649 patent.

96. On information and belief, Slayback will encourage another's infringement of the '649 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its ANDA Product as described in ANDA No. 212296, which is covered by certain claims of the '649 patent.

97. Slayback's acts of infringement will be done with knowledge of the '649 patent and with the intent to encourage infringement.

98. The foregoing actions by Slayback will constitute active inducement of infringement of the '649 patent.

99. On information and belief, Slayback knows or should know that its ANDA Product as described in ANDA No. 212296 will be especially made or especially adapted for use in an infringement of the '649 patent, and is not a staple article or commodity suitable for substantial non-infringing use.

100. The commercial manufacture, use, sale, offer for sale, and/or importation of Slayback's ANDA Product described in ANDA No. 212296 will contribute to the actual infringement of the '649 patent.

101. On information and belief, Slayback knows or should know that its offer for sale, sale, and/or importation of its ANDA Product as described in ANDA No. 212296 will contribute to the actual infringement of the '649 patent.

102. The foregoing action by Slayback will constitute contributory infringement of the '649 patent.

103. On information and belief, Slayback intends to, and will, actively induce and contribute to the infringement of the '649 patent when ANDA No. 212296 is approved, and plans and intends to, and will do so immediately and imminently upon approval.

104. Kythera is entitled to a declaratory judgement that future commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's ANDA Product as described in ANDA No. 212296 will induce and/or contribute to the infringement of the '649 patent.

105. The commercial manufacture, use, offer for sale, sale and/or importation of Slayback's ANDA Product described in ANDA No. 212296, which will actively induce and/or contribute to infringement of the '649 patent, in violation of Kythera's patent rights, will cause harm to Kythera for which damages are inadequate.

106. Unless Slayback is enjoined from actively inducing and contributing to the infringement of the '649 patent, Kythera will suffer irreparable injury for which damages are an inadequate remedy.

107. On information and belief, despite having actual notice of the '649 patent, Slayback continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '649 patent in disregard of Kythera's rights, making this case exceptional and entitling Kythera to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count VII

(Infringement of the '058 Patent Under 35 U.S.C. § 271(e)(2) by Slayback's ANDA Product)

108. Kythera incorporates each of the preceding paragraphs as if fully set forth herein.

109. Pursuant to 35 U.S.C. § 271(e)(2)(A), Slayback has committed an act of infringement with respect to the '058 patent by submitting ANDA No. 212296 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Slayback ANDA Product in the United States prior to the expiration of the '058 patent.

110. Slayback's commercial manufacture, use, offer for sale, sale, and/or importation of the Slayback ANDA Product as described in ANDA No. 212296 prior to the expiration of the '058 patent would constitute infringement of the '058 patent.

111. On information and belief, Slayback became aware of the '058 patent no later than the date on which that patent was listed in the Orange Book.

112. On information and belief, Slayback knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product will actively induce and contribute to the actual infringement of the '058 patent.

113. On information and belief, Slayback knows or should know that its ANDA Product will be especially made for or especially adapted for use in infringement of the '058 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product will actively contribute to the actual infringement of the '058 patent.

114. The commercial manufacture, use, offer for sale, sale and/or importation of Slayback's ANDA Product as described in ANDA No. 212296 in violation of Kythera's patent rights will cause harm to Kythera for which damages are inadequate.

Count VIII

(Declaratory Judgment of Infringement of the '058 Patent under 35 U.S.C. § 271(a) by Slayback's ANDA Product)

115. Kythera incorporates each of the preceding paragraphs as if fully set forth herein.

116. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

117. There is an actual case or controversy such that the Court may entertain Kythera's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

118. The commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's ANDA Product described in ANDA No. 212296 will constitute an act of direct infringement of one or more claims of the '058 patent.

119. On information and belief, Slayback will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product described in ANDA No. 212296 immediately and imminently upon approval of ANDA No. 212296.

120. The foregoing actions by Slayback will constitute infringement of the '058 patent.

121. Slayback will commit those acts of infringement without license or authorization.

122. Kythera is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Slayback's ANDA Product described in ANDA No. 212296 by Slayback will infringe the '058 patent.

123. Unless Slayback is enjoined from infringing the '058 patent, Kythera will suffer irreparable injury for which damages are an inadequate remedy.

Count IX

(Declaratory Judgment of Infringement of the '058 Patent under 35 U.S.C. § 271(b) and (c) by Slayback's ANDA Product)

124. Kythera incorporates each of the preceding paragraphs as if fully set forth herein.

125. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

126. There is an actual case or controversy such that the Court may entertain Kythera's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

127. Slayback has knowledge of the '058 patent.

128. On information and belief, Slayback became aware of the '058 patent no later than the date on which that patent was listed in the Orange Book.

129. On information and belief, Slayback has acted with full knowledge of the '058 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '058 patent.

130. The commercial manufacture, use, sale, offer for sale, and/or importation of Slayback's ANDA Product as described in ANDA No. 212296 will induce the actual infringement of the '058 patent.

131. On information and belief, Slayback knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its ANDA Product described in ANDA No. 212296 will actively induce the actual infringement of the '058 patent.

132. On information and belief, Slayback will encourage another's infringement of the '058 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its ANDA Product as described in ANDA No. 212296, which is covered by certain claims of the '058 patent.

133. Slayback's acts of infringement will be done with knowledge of the '058 patent and with the intent to encourage infringement.

134. The foregoing actions by Slayback will constitute active inducement of infringement of the '058 patent.

135. On information and belief, Slayback knows or should know that its ANDA Product as described in ANDA No. 212296 will be especially made or especially adapted for use in an infringement of the '058 patent, and is not a staple article or commodity suitable for substantial non-infringing use.

136. The commercial manufacture, use, sale, offer for sale, and/or importation of Slayback's ANDA Product described in ANDA No. 212296 will contribute to the actual infringement of the '058 patent.

137. On information and belief, Slayback knows or should know that its offer for sale, sale, and/or importation of its ANDA Product as described in ANDA No. 212296 will contribute to the actual infringement of the '058 patent.

138. The foregoing action by Slayback will constitute contributory infringement of the '058 patent.

139. On information and belief, Slayback intends to, and will, actively induce and contribute to the infringement of the '058 patent when ANDA No. 212296 is approved, and plans and intends to, and will do so immediately and imminently upon approval.

140. Kythera is entitled to a declaratory judgement that future commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's ANDA Product as described in ANDA No. 212296 will induce and/or contribute to the infringement of the '058 patent.

141. The commercial manufacture, use, offer for sale, sale and/or importation of Slayback's ANDA Product described in ANDA No. 212296, which will actively induce and/or

contribute to infringement of the '058 patent, in violation of Kythera's patent rights, will cause harm to Kythera for which damages are inadequate.

142. Unless Slayback is enjoined from actively inducing and contributing to the infringement of the '058 patent, Kythera will suffer irreparable injury for which damages are an inadequate remedy.

143. On information and belief, despite having actual notice of the '058 patent, Slayback continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '058 patent in disregard of Kythera's rights, making this case exceptional and entitling Kythera to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Exceptional Case

144. Slayback was aware of at least the '593, '649, and '058 patents prior to filing its ANDA for a generic version of Kythera's Kybella® product and sending the Notice Letter to Kythera.

145. The actions of Slayback render this an exceptional case under 35 U.S.C. § 285.

Jury Trial Demand

Pursuant to Federal Rule of Civil Procedure 38(b), Kythera hereby demands a trial by jury of all issues so triable.

Prayer for Relief

Kythera respectfully prays that this Court grant the following relief:

- a. A finding that the '593, '649, and '058 patents are valid and enforceable;
- b. That a judgment be entered that Slayback has infringed the '593, '649, and '058 patents under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under Section 505(j) of the FDCA;

c. That a declaration be issued under 28 U.S.C. § 2201 that if Slayback, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale and/or importation of Slayback's ANDA Product described in ANDA No. 212296, it will constitute an act of infringement of the '593, '649, and '058 patents under 35 U.S.C. § 271(a), (b), and (c);

d. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Slayback's ANDA shall be a date which is not earlier than the latest expiration date of the '593, '649, and '058 patents, including any extensions or periods of exclusivity;

e. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Slayback, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '593, '649, and '058 patents until the expiration date of the '593, '649, and '058 patents, including any extensions or periods of exclusivity;

f. If Slayback attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Slayback's ANDA Product disclosed in its ANDA prior to the expiration of the '593, '649, and '058 patents, including any extensions or periods of exclusivity, a preliminary injunction be entered enjoining such conduct;

g. If Slayback attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Slayback's ANDA Product disclosed in its ANDA prior to the expiration

of the '593, '649, and '058 patents, including any extensions or periods of exclusivity, a judgment awarding Kythera damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

h. An accounting for any infringing sales not presented at trial and an award by the Court of any additional damages for any such infringing sales;

i. A finding that this action for infringement is an exceptional case under 35 U.S.C. § 285, and that Kythera be awarded reasonable attorneys' fees and costs; and

j. An award of any such other and further relief as the Court may deem just and proper.

Dated: November 9, 2018

Respectfully submitted,

s/Liza M. Walsh

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Counsel for Plaintiff

KYTHERA BIOPHARMACEUTICALS, INC.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 401

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiff that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: November 9, 2018

Respectfully Submitted,

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KYTHERA BIOPHARMACEUTICALS, INC.

RULE 201.1 CERTIFICATION

I hereby certify that, to the best of my knowledge, the above captioned matter is not subject to compulsory arbitration in that Plaintiff seeks, *inter alia*, injunctive relief.

Dated: November 9, 2018

Respectfully Submitted,

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